COVID-19 Vaccine Information Brief

April 8, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Vaccine Information Brief will be April 22, 2022

IMPORTANT/NEW COVID-19 Vaccine Information

- HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund
- Moderna Ancillary Kit - Update
- COVID-19 Vaccine Interim Clinical Considerations - Updated March 30, 2022
- White House Announces New COVID-19 Website
- Updated and New COVID-19 Vaccine Web Resources
- Clinical Guidance on Pediatric Needle Usage
- Preventing Fraud or Theft of COVID-19 Vaccines and Vaccination Cards
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- IRIS COVID-19 Provider Vaccine Inventory Management
- Shelf Life Extension for Johnson & Johnson's Janssen COVID-19 Vaccine
- Vaccine Expiration Date Resources
- V-Safe After Vaccination Health Checker

Statement Regarding Exhaustion of Funding for Uninsured Program and Coverage Assistance Fund

The HRSA COVID-19 Uninsured Program has stopped accepting claims due to a lack of sufficient funds. **Confirmation of receipt of claim submission does not mean the claim will be paid.** Claims submitted by these deadlines will be paid subject to eligibility and availability of funds.

Unfortunately, IDPH does not have any information about efforts to continue to sustain this program. Provider questions can be directed to the HRSA COVID-19 Uninsured Program Provider Support Line: 866-569-3522, whose hours of operation are 8:00 am to 10:00 pm Central Time, Monday through Friday. For additional information, see COVID-19 Uninsured Program Claims Submission Deadline FAQs.

IDPH has received questions regarding the provider's ability to refuse COVID-19 vaccine to uninsured patients. CDC strongly encourages providers to stay in the CDC COVID-19 Vaccination Program and CDC expects participating providers will continue to administer these life saving vaccines at no cost to patients to ensure equitable access for all individuals. The COVID-19 Vaccination Program Provider Requirements website does offer guidance:

All organizations and providers participating in the CDC COVID-19 Vaccination Program:

- **must** administer COVID-19 Vaccine at no out-of-pocket cost to the recipient
- may **not** deny anyone vaccination based on the vaccine recipient's coverage status or network status
- may **not** charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided
- may **not** require additional medical services to receive COVID-19 vaccination
- **may** seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient, such as:
    - vaccine recipient's private insurance company
    - Medicare or Medicaid reimbursement
    - HRSA COVID-19 Uninsured Program for non-insured vaccine recipients
- **may not seek any reimbursement, including through balance billing, from the vaccine recipient**

Moderna Ancillary Kit - Update

Moderna COVID-19 vaccine shipments will now come with ***one ancillary kit*** (1 ancillary kit to 1 carton of vaccine, instead of 2 ancillary kits to 1 carton of vaccine). **This change will take effect with orders placed beginning on Monday, April 11, 2022, at 10:00 am ET.**

COVID-19 Vaccine Interim Clinical Considerations - Updated March 30, 2022

CDC updated the Interim Clinical Considerations for Use of COVID Vaccines in the United States to include guidance that says individuals **12 years and older who *are* moderately or severely immunocompromised and adults 50 years and older who are *not* moderately or severely immunocompromised "may choose to receive" a second mRNA booster** 4 months after their first booster dose.

The updated guidance also states that people 18-49 who are not moderately or severely immunocompromised who received the **Janssen vaccine for both primary and booster doses "may receive" a second mRNA booster dose** 4 months after the first Janssen booster. The summary of recent changes include:

- Added guidance that people ages 12 years and older who are moderately or severely immunocompromised may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose
- Added guidance that adults ages 50 years and older who are **not** moderately or severely immunocompromised may choose to receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first booster dose
- Added guidance that people ages 18–49 years who are **not** moderately or severely immunocompromised and who received Janssen COVID-19 Vaccine as both their primary series dose and booster dose may receive a second booster dose using an mRNA COVID-19 vaccine at least 4 months after the first Janssen booster dose
- Further clarification of safety issues including those related to multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A) and myocarditis
- Updated information on the availability of Moderna COVID-19 Vaccine supplied in a vial with a blue cap (0.5 mL dosage volume) for administration of a 50 µg booster dose.

White House Announces New COVID-19 Website

The Biden Administration is launching COVID.gov, a new one-stop shop website to help all people in the United States gain even better access to lifesaving tools like vaccines, tests, treatments, and masks, as well as get the latest updates on COVID-19 in their area. COVID.gov also provides people an easy way to find the level of COVID-19 in their community and will help people access pharmacies and community health centers across the nation where people can get tested for COVID-19 and receive appropriate treatments if they need them.

Updated and New COVID-19 Vaccine Web Resources

The following COVID-19 vaccine resources have recently been updated.

- COVID-19 Vaccine Booster Shots
- Pfizer-BioNTech COVID-19 Vaccine (also known as COMIRNATY) Overview and Safety
- Frequently Asked Questions about COVID-19 Vaccination
- COVID-19 Vaccines for Moderately or Severely Immunocompromised People
- Stay Up to Date with Your COVID-19 Vaccines

Clinical Guidance on Pediatric Needle Usage

The Advisory Committee on Immunization Practices recommends using a 1-inch needle for children 1 year of age and older when administering vaccines to ensure the vaccine is deposited well into the muscle tissue. A 5/8-inch needle may be used in some circumstances if the child's skin is stretched tightly, and subcutaneous tissues are not bunched.

Providers should use professional judgment and for the rare situation in which a 5/8-inch needle is required, one can be obtained from the facility's inventory and replaced with supplies from the ancillary supply kits. Ancillary kits contain only 1-inch needles. Please refer to the following webpages for more guidance:

- Needle gauge and length, all ages:
  - https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf
- IM injection, infants:
  - https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-Infants-508.pdf
- IM injection, 1-2 years
  - https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-1-2-Years-508.pdf
- IM injection, 3-6 years:
  - https://www.cdc.gov/vaccines/hcp/admin/downloads/IM-Injection-3-6-Years.pdf

General Best Practice Guidelines on Immunizations **- ACIP Vaccine Administration Guidelines for Immunization | CDC**

Preventing Fraud or Theft of COVID-19 Vaccines and Vaccination Cards

To prevent COVID-19 Vaccination Cards from being stolen, fraudulently reproduced, and illegally sold to reflect full vaccination status for someone who has not received a COVID-19 vaccine, please consider the following strategies:

- Always secure **COVID-19 vaccine vials and vaccination cards** to protect them from inappropriate distribution.
- Monitor both the inventory of COVID-19 vaccine and blank vaccination cards and keep them locked up when not being used.

IDPH encourage reporting suspected fraud and theft incidences to local law enforcement agencies and to the HHS Office of Inspector General and/or the FBI as listed below:

- HHS Office of Inspector General (1-800-HHS-TIPS or www.oig.hhs.gov)
- Federal Bureau of Investigation Electronic Tip Form (http://tips.fbi.gov)

Surplus Vaccination Cards

Please shred or destroy unused surplus cards. If unable to do so, providers must keep extra vaccination cards in a secure location (under lock and key).

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

At this time, the Medical Affairs team is continuing to educate providers on Purple, Gray, and Orange caps as well as medical updates. To access dates and links for upcoming training sessions, please visit: **https://www.pfizermedicalinformation.com/en-us/medical-updates.**

IRIS COVID-19 Provider Vaccine Inventory Management

IRIS vaccine inventory management is a critical component of the pandemic vaccine response. All COVID-19 Vaccine Providers are required to report COVID-19 vaccine doses administered to IRIS which deducts from IRIS inventory. Maintaining accurate inventory impacts the state's ability to report accurate inventory to federal partners. Additionally, this also impacts the state's vaccine thresholds and the amount of vaccine available for all providers. Providers should make it a practice to regularly check inventory for expired vaccine and immediately remove expired inventory to prevent it from being administered. Please review these IRIS inventory management best practices to ensure accurate vaccine inventory.

- Ensure Vaccine Redistributions are accurately reported.
    - All COVID-19 vaccine transfers between providers MUST be completed and approved by IDPH. Please see the *Vaccine Redistribution Instructions*.
    - Providers should NOT physically transfer COVID-19 vaccine without prior IDPH approval.
- Verify all data entry in IRIS is up to date.
    - Doses administered are required to be reported to IRIS within 24 hours of vaccine administration.
- Verify data exchange between IRIS and the organization's Electronic Health Record (EHR) has worked appropriately.
    - IRIS Admin users can use the *Doses Not Deducted Report* to view and update doses of COVID-19 vaccines not deducted from IRIS inventory.

- Report vaccine wastage in IRIS.
    - Verify all vaccine wastage is documented appropriately using the approved adjustment reasons included in the *Adjusting COVID-19 Vaccine Inventory for Wastage* instructions.
    - **VACCINE WASTAGE ADJUSTMENT REASONS CANNOT BE USED TO CORRECT VACCINE INVENTORY FOR UNACCOUNTED DOSES**.

If you have questions regarding IRIS and vaccine inventory, contact the IRIS Help Desk at 1-800-374-3958.

Shelf Life Extension for Johnson & Johnson's Janssen COVID-19 Vaccine

The Food & Drug Administration announced the approval of a shelf life extension for the Johnson & Johnson's Janssen COVID-19 vaccine for **an additional three months**. The shelf life of this vaccine has been updated from 6 months to **9 months**. This shelf life extension applies to refrigerated vials of J&J/Janssen COVID-19 vaccine that have been held in accordance with the manufacturer's storage conditions.

This shelf life extension applies to all inventory dated to expire on March 7, 2022 or later. Vaccine providers should visit the Janssen COVID-19 Vaccine Expiry Checker webpage to confirm expiration dates prior to March 7, 2022 before disposing of J&J vaccine. J&J did receive a shelf life extension for certain lots dated prior to March 7, 2022.

COVID-19 vaccines authorized under an EUA do not have fixed expiration dates, and expiration dates may be extended as more stability data becomes available. This decision is based on data from ongoing stability assessment studies, which have demonstrated that the vaccine is stable at 9 months when refrigerated at temperatures of 36° - 46° Fahrenheit (2° - 8° Celsius). **Healthcare providers should always check the manufacturer's website to obtain the most up-to-date expiration dates for the COVID-19 vaccines in inventory.**

Reporting vaccine wastage in IRIS:

- Verify all vaccine wastage is documented appropriately using the approved adjustment reasons included in the *Adjusting COVID-19 Vaccine Inventory for Wastage* instructions.
- **VACCINE WASTAGE ADJUSTMENT REASONS CANNOT BE USED TO CORRECT VACCINE INVENTORY FOR UNACCOUNTED DOSES**.

If healthcare providers have questions regarding IRIS and vaccine inventory, contact the IRIS Help Desk at 1-800-374-3958.

Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958.

For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of 12/31/2069 to serve as a *placeholder date*. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. **It is important for healthcare providers to update vaccine expiration dates in IRIS.**

The Pfizer COVID-19 vaccine:

It is important for all healthcare providers to double check all shelf life extensions for all Pfizer products. Pfizer does not have an expiration date look up tool for these vaccines. The date on the label is **NOT** the expiration date, instead, each vial has the lot number and date of manufacture printed on the label. Pfizer does provide guidance for expiration dates on their website**.**

- Regardless of storage condition, GRAY CAP and ORANGE CAP vaccine vials should not be used after 9 months from the **date of manufacture** printed on the vial and cartons.
- The PURPLE CAP vaccine vials with an **expiry date** of September 2021 - February 2022 (printed on the label) may remain in use for 3 months beyond the printed date if vials are maintained in approved storage conditions (-90°C to -60°C, -130°F to -76°F).
- Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 (ORANGE CAP) years of age may be stored at refrigerated temperatures between 2°C and 8°C (36°F and 46°F) for up to 10 weeks. **Vaccine initially distributed is nearing or has met the 10-week beyond-use date (BUD).**
    - **Reminders for providers:**
        - Vaccine may be stored in a refrigerator unit between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.
        - Do NOT use vaccines stored in the refrigerator after 10 weeks. Discard appropriately.
        - Use a tracking system to ensure the vaccine is not used after the BUD. CDC has tracking labels to monitor storage times at Pfizer-BioNTech COVID-19 Vaccine (5 Through 11 Years of Age) | CDC

Expiry information for Ages 5 through 11 DILUTE BEFORE USE Orange Cap presentation* and Ages 12 years and older DO NOT DILUTE Gray Cap presentation*

Printed Manufacturing Date	9-Month Expiry Date
06/2021	28-Feb-2022
07/2021	31-Mar-2022
08/2021	30-Apr-2022
09/2021	31-May-2022
10/2021	30-Jun-2022
11/2021	31-Jul-2022
12/2021	31-Aug-2022
01/2022	30-Sep-2022
02/2022	31-Oct-2022
03/2022	30-Nov-2022

Expiry information for Ages 12 years and older DILUTE BEFORE USE Purple Cap presentation†

Printed Expiry Date	Updated Expiry Date
September 2021	December 2021
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022
March 2022	June 2022

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.jnj/

Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to www.modernatx.com/covid19vaccine-eua/

CDC's COVID-19 Vaccine Expiration Date Tracking Tool can help providers keep track of the expiration date by lot number.

V-safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: posted on the vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- V-safe after vaccination health checker website
- V-safe Print Resources
- V-safe Poster-11x17
- Vaccine Adverse Event Reporting System (VAERS)